

Serial No. 09/091,958
Filed: June 7, 1999
Examiner Z. Fay
Group Art Unit: 1614

Remarks

Claim 1 has been amended. With this amendment, the claims pending are claims 1, 2, and 5-20. Support for the amendment to claim 1 is found in the specification as originally filed. Specifically, support for the volume size limitation can be found at page 3. See paragraph 4 of the attached Declaration of Jonathan Embleton. Thus, no new matter is added by this amendment.

Although Applicants maintain that the claims were sufficient to overcome all the prior art as they existed after their last response, Applicants have made the amendments herein to distinguish the invention even further from the art. Consequently, it is respectfully submitted that the claims as amended are clearly nonobvious over the references relied on by the Examiner, U.S. Patent No. 4,158,361 (Kotuby) and UK Patent Application GB 2255918 (Dunne). Claim 1 requires a predetermined liquid volume in the form of a jet or stream of droplets and that substantially the entire dosage form is delivered to the target. The jet or each droplet "is of a size sufficient to sustain momentum along a substantially horizontal path 5 cms in length from a discharge velocity of up to 25 m/sec from the delivery device." In addition, as amended, the claim

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requires that "the jet or stream of droplets is a moving volume of liquid having a length and diameter that remain substantially unchanged between exiting the delivery device and contacting the target site." Neither Kotuby nor Dunne teaches or suggests such a dosage form.

Both Kotuby and Dunne disclose a device that discharges a spray, not a jet or stream of droplets as required by the claims. As is explained in the Embleton declaration, the references disclose sprays, i.e., a volume of droplets that lacks the momentum required in the claims and also disperses over distance. In other words, the sprays of Kotuby and Dunne are not volumes that have length and diameter that remain substantially unchanged after exiting the delivery device. Kotuby and Dunne clearly fail to suggest the claimed invention.

Further, it is the coherence of the volume of liquid, i.e., that its length and diameter remain substantially unchanged, that in combination with the other limitations in the claims allows the stream to achieve impulse delivery in a controlled and targeted fashion that does not provoke the blink response.

Applicants previously discussed the significance of the claim limitations as they relate to administration of ophthalmic compositions. As set forth in the specification on pages 1-4,

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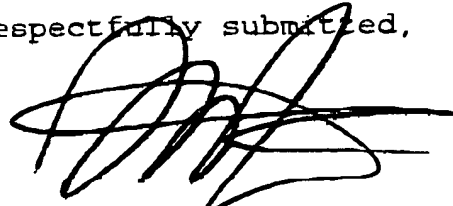
it is important that the dosage form have constant size and sufficient momentum to be accurately targeted and beat the "blink response." The "blink response" is the natural reaction of the human eye to close in response to the imminent or actual impact of any item. The claims are directed to a dosage form capable of defeating the "blink response" by ensuring that the entire quantity of treatment liquid in the dosage form reaches the eye before it reflexively closes.

Neither the Kotuby device nor the Dunne device generates such a dosage form. Neither reference relates to a device for administering "a predetermined liquid volume" or to a device capable of creating "a jet or stream of droplets" as it is defined in claim 1, i.e., "a moving volume of liquid having a length and diameter that remain substantially unchanged between exiting the delivery device and contacting the target site." Clearly, neither reference creates a "dosage form" that can be substantially entirely delivered to the target. There is nothing in either reference that suggests targeted predetermined moving volumes of liquid having a substantially unchanging length and diameter. The claims are therefore neither anticipated nor obvious in view of Kotuby and Dunne and withdrawal of the rejection is respectfully requested.

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Allowance of the claims and passage of the case to issue are respectfully solicited. Should the Examiner believe a discussion of this matter would be helpful, she is invited to telephone the undersigned at (312) 913-0001.

Respectfully submitted,



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Marked-up version of claims showing changes

1. (Three times amended) A dosage form useful in ophthalmic treatment having a predetermined liquid volume of from about 3 to 20 μ l, the dosage form being a jet or stream of droplets of treatment fluid, each droplet having an ophthalmologically active compound in suspension or solution and wherein the jet or each droplet of a size sufficient to sustain momentum along a substantially horizontal path 5 cms in length from a discharge velocity of up to 25 m/sec from the delivery device, wherein substantially the entire dosage form is delivered to the target site and where the jet or stream of droplets is a moving volume of liquid droplets, where the volume has a length and diameter that remain substantially unchanged between exiting the delivery device and contacting the target site.